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10 **UNITED STATES DISTRICT COURT**
11 **EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND
DRUG ADMINISTRATION, et al.,

16 Defendants.
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NO. 1:23-cv-03026-TOR

PLAINTIFF STATES' REPLY IN
SUPPORT OF MOTION TO
SUPPLEMENT THE
ADMINISTRATIVE RECORD

02/20/2024
Without Oral Argument

PLAINTIFF STATES' REPLY IN
SUPPORT OF MOTION TO
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ADMINISTRATIVE RECORD

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I. INTRODUCTION

This Court has already ruled that the formal citizen petition submitted in 2022 by ACOG and 48 other organizations was “before FDA” in connection with its decision to impose the 2023 mifepristone REMS. This petition, ECF No. 61-1, provides evidence showing that each REMS element is medically unnecessary and unduly burdensome, and asks FDA to lift the REMS entirely. FDA’s insistence that it “did not consider” this citizen petition—which FDA denied on the very same day it re-imposed a REMS on mifepristone—conflicts with this Court’s prior ruling, ECF No. 80 at 16-17, and contradicts FDA’s own contemporaneous admission that it “carefully considered” the petition. Tellingly, FDA fails to even address this compelling evidence that it did, in fact, consider the petition. Similarly, the record is incomplete without—at a minimum—the Turnaway Study report cited in the letter to FDA from the Turnaway Study’s author.

Alternatively, even if FDA turned a blind eye to these materials when it re-imposed a REMS on mifepristone, they should still be added to the record because they will demonstrate that FDA failed to consider major issues it was statutorily obligated to consider: that the REMS restrictions do not make mifepristone safer, are inconsistent with the regulation of riskier drugs, and are unduly burdensome.

II. ARGUMENT

A. ACOG’s Citizen Petition Was “Before FDA,” as the Court Has Ruled

As discussed at length in the Plaintiff States’ Motion, this Court previously ruled that ACOG’s 2022 citizen petition to lift the mifepristone REMS was “before

1 FDA” in connection with FDA’s decision to impose the current REMS, such that
2 it would be futile to submit yet another citizen petition seeking the same relief.
3 ECF No. 133 at 3-4, 7-8 (citing ECF No. 80 at 16-17). Moreover, FDA denied
4 ACOG’s petition on the very same day it imposed the current REMS, which is
5 compelling evidence that the agency directly or at least indirectly considered the
6 petition in connection with the action it took that day. Unable to deny the Court’s
7 prior ruling or its own prior acknowledgement that it “carefully considered” the
8 petition, FDA’s Opposition simply ignores both.

9 Instead, the agency insists that it “did not consider” ACOG’s petition in
10 connection with its decision to impose the current REMS. ECF No. 139 at 5. To
11 support this contention, FDA claims that it actually decided to impose the 2023
12 mifepristone REMS all the way back in 2021, and that ACOG’s 2022 citizen
13 petition was received “after FDA’s 2021 determination” to re-impose a REMS. *Id.*
14 at 6. FDA’s suggestion that documents received after 2021 somehow did not or
15 could not inform its 2023 agency action is belied by FDA’s own produced record,
16 which includes numerous documents that post-date 2021. One such document is a
17 June 21, 2022, letter to FDA from ACOG and the American Medical Association,
18 which is part of the produced record along with 28 documents that are cited in that
19 letter. *See* ECF No. 127 at 41-44 (Index listing 2023 SUPP 000032-037 with
20 28 sub-listings). FDA’s inclusion of these post-2021 documents in the record
21 demonstrates that the agency either directly or indirectly considered them. *See* ECF
22 No. 139 at 7 (conceding that, at a minimum, the record “designated” by the agency

1 consists of documents the agency “directly or indirectly considered”). Since FDA
2 admittedly considered ACOG’s post-2021 letter, its suggestion that it somehow
3 could not have considered ACOG’s post-2021 citizen petition falls flat.

4 FDA next pivots and resurrects an unsuccessful argument it made at the
5 preliminary injunction stage, claiming that it did not consider ACOG’s petition in
6 connection with its decision to re-impose a REMS because the petition was
7 focused, in part, on the use of mifepristone for miscarriage management. *See* ECF
8 No. 139 at 6-7; ECF No. 51 at 18-19. But as the Plaintiff States previously
9 explained, ACOG’s petition in fact asked FDA to eliminate the REMS as medically
10 unnecessary and unduly burdensome for *all* uses of the drug—which is the “gold
11 standard” for both abortion and miscarriage management—and cited evidence to
12 support removing the REMS entirely. ECF No. 60 at 4 (citing ECF No. 61-1); ECF
13 No. 61-7 at 3; *see also* ECF No. 3 at 12 (summarizing the petition’s requests that
14 the three elements of the current REMS are “medically unnecessary,” “redundant,”
15 provide “no benefit to patient safety,” and are unduly burdensome). Appropriately
16 accounting for the ACOG petition as a whole, including this and other specific
17 information that was “before FDA” as of January 2023, the Court concluded that
18 it would be futile to require the Plaintiff States to submit yet another citizen petition
19 asking FDA to remove the mifepristone REMS. ECF No. 80 at 16-17.

20 Against this Court’s prior findings, a different court’s passing comment that
21 ACOG’s citizen petition is “not directly relevant” to the mifepristone REMS
22 cannot salvage FDA’s efforts to suppress the petition. *See* ECF No. 139 at 8-9.

1 This comment is pulled out of context by FDA, because the Western District of
 2 Virginia’s conclusion was the same as this Court’s—that further exhaustion would
 3 be futile, “as FDA has demonstrated by its past actions and prior findings that it
 4 will not grant the relief sought by Plaintiffs.” *Whole Woman’s Health All. v. U.S.*
 5 *Food & Drug Admin.*, No. 3:23-cv-00019, 2023 WL 5401885, at *6-7 (W.D. Va.
 6 Aug. 21, 2023) (“agree[ing] with” this Court’s similar conclusion). Moreover, to
 7 the extent the district court’s comment in *Whole Woman’s Health* was based on an
 8 overly narrow reading of ACOG’s petition, that cannot overcome this Court’s own
 9 prior conclusion that ACOG’s petition and its supporting studies were “already put
 10 forth before FDA[.]” ECF No. 80 at 16-17.

11 Further, as previously noted, FDA admitted on January 3, 2023, that it had
 12 “carefully considered” ACOG’s citizen petition. ECF No. 133 at 2, 8-9 (quoting
 13 ECF No. 1-20 at 2). This admission means that FDA necessarily directly
 14 considered the petition’s request to remove the REMS entirely and the supporting
 15 evidence of the same—not just the request to add an additional indication to the
 16 mifepristone label. *See* ECF No. 61-1 at 12-17 (discussing each REMS element in
 17 turn, seeking the removal of each, and concluding that “Existing Data Demonstrate
 18 that a Removal of All REMS Requirements Will Not Harm Patient Safety”). FDA
 19 does not dispute that its denial letter acknowledged “careful[] consider[ation]” of
 20 ACOG’s citizen petition, nor could it: FDA acknowledges that ECF No. 1-20 is its
 21 own denial letter. ECF No. 139 at 6-7. Nor is it plausible for FDA to now claim
 22 that the ACOG petition is entirely unrelated to the current REMS when FDA

1 denied the petition’s request to remove the REMS on the *very same day* it imposed
 2 the current REMS. *See* ECF No. 133 at 2, 8-9. Notably, FDA offers no explanation
 3 for the telling timing of its two closely related actions taken by the *same* office
 4 within FDA (the Center for Drug Evaluation and Research) concerning the *same*
 5 REMS program for the *same* drug on the *same* day. Because there is no dispute
 6 that FDA considered ACOG’s petition at the very same time it was imposing the
 7 2023 REMS, the petition is part of the record. *See Ctr. for Food Safety v. EPA*,
 8 No. 23-cv-02714-SI, 2023 WL 8813528, at *3 (N.D. Cal. Dec. 19, 2023)
 9 (“materials provided to an agency during a decision-making process related to the
 10 subject matter of that decision” are properly part of the administrative record).

11 Last but certainly not least, the fact that ACOG’s citizen petition is properly
 12 part of the administrative record compels the conclusion that the documents cited
 13 therein are also properly part of the record. FDA’s only argument for excluding
 14 these documents is that it did not consider the petition itself. ECF No. 139 at 8-9
 15 (arguing that it should not be “surprising” that the “ACOG Citizen Petition
 16 documents” were not included because the petition supposedly was limited to the
 17 miscarriage indication and not the REMS program). Indeed, FDA admits that it
 18 *does* consider “references” cited in “letters” directed to it. *Id.* at 11 n.3. The
 19 produced record confirms this: throughout, citizen petitions, letters, and other
 20 direct communications to FDA are routinely accompanied by the documents cited
 21 within those communications. *See, e.g.*, ECF No. 127 at 7-10 (Index listing 2019
 22 CP 000001-027 with 52 sub-listings); *id.* at 15-16 (Index listing 2021 ED 000001-

1 003 with nine sub-listings); *id.* at 16-17 (Index listing 2021 ED 000073-077 with
 2 10 sub-listings); *id.* at 17 (Index listing 2021 ED 000361-362 with three sub-
 3 listings); *id.* at 17-18 (Index listing 2021 ED 000434-438 with six sub-listings).
 4 This pattern repeats throughout the 46-page Index of the produced administrative
 5 record. *See generally id.* FDA claims that it does not consider “the references cited
 6 within the references” in letters it receives, ECF No. 139 at 11 n.3, but the materials
 7 at issue here—studies directly cited in the ACOG petition—fall squarely within
 8 the former category that FDA *concedes* are appropriately part of the record.
 9 Because the ACOG citizen petition was before FDA when it decided to re-impose
 10 the REMS—and because the evidence cited therein (including but not limited to
 11 the 2022 study in the New England Journal of Medicine on Canada’s successful
 12 elimination of their REMS-like restrictions on mifepristone, *see* ECF No. 61-1 at
 13 18, 29 n.52) is directly relevant to the petition’s request to lift the REMS entirely,
 14 the documents cited in the petition are properly part of the record.

15 In sum, FDA’s assertion that “Plaintiffs have not provided *any* evidence”
 16 that the agency considered the ACOG citizen petition, ECF No. 139 at 8, is simply
 17 untrue. (1) This Court’s prior ruling, which was based on (2) the formal citizen
 18 petition citing evidence that supports removal of the REMS entirely, which (3)
 19 FDA admittedly “carefully considered” and responded to and that (4) FDA denied
 20 on the very same day it re-imposed a REMS, all demonstrate that FDA directly or
 21 indirectly considered the citizen petition—and the documents cited therein—in
 22 connection with the challenged agency action.

B. The Turnaway Study Is Cited and Discussed in a Letter to FDA

As discussed above, FDA concedes, and the produced record confirms, that it *does* consider information cited in “letters” directed to it. And as discussed in the Plaintiff States’ Motion, the Turnaway Study was cited and discussed in a letter to FDA signed by the study’s author, Advancing New Standards in Reproductive Health (ANSIRH). ECF No. 133 at 9; ECF No. 1-9; ECF No. 35 ¶ 95 & n.19. The Turnaway Study’s data—including the findings that being denied an abortion results in worse health, family, and financial outcomes—are what provide the evidentiary basis for the summaries and references found throughout the produced record. *See* ECF No. 133 at 5; ECF No. 135 ¶ 6.c (listing 35 places the Turnaway Study is cited in the administrative record). While the Turnaway Study’s data is undoubtedly relied upon by numerous studies given its groundbreaking significance, *see* ECF No. 139 at 10, this is no basis for FDA’s refusal to complete the record. *Contra id.* At a minimum, the Turnaway Study report cited in the ANSIRH letter to FDA was before the agency and should be added to the record. ECF No. 1-9; Second Beneski Decl. ¶¶ 4, 5 & Exs. B, C.

And regardless of whether the record is completed or supplemented in this way, FDA effectively admits it *knows* that unduly restricting access to mifepristone harms the underserved patient populations it is statutorily required to consider. *See* ECF No. 139 at 13-14. On the merits, FDA will have to explain why it nevertheless retained a medically unnecessary and harmful REMS with ETASU to artificially restrict the availability of this extraordinarily safe medication.

C. Evidence of FDA Ignoring Key Factors Is Highly Relevant

Because the materials at issue were demonstrably before FDA, the Court need not determine whether “supplementation” as opposed to “completion” of the record is necessary. But the supplementation standard is satisfied here, too.

This is not an effort to “pad the record” with evidence of some minor point that FDA missed. *Contra* ECF No. 139 at 13. This case is about FDA ignoring *major* aspects of the problem in making a decision that failed to follow the law and cannot be reconciled with mifepristone’s outstanding safety record, particularly as compared with other medications not burdened with a REMS. At the preliminary injunction stage, the Plaintiff States argued that a REMS with ETASU for mifepristone is unjustifiable under the statutory limits Congress placed on FDA’s authority. *See* ECF No. 80 at 18-20. In response to this argument, this Court noted FDA “d[id] not address whether mifepristone qualifies for ETASU, asserting it need *only* determine whether modifications [to the existing REMS program] are appropriate under 21 U.S.C. § 355-1(g)(4)(B).” *Id.* at 20 (emphasis added). The Court rejected FDA’s crabbed view of its statutory obligations, ruling that “it would be contrary to the plain language of the statute that the agency need not consider arguments that mifepristone’s REMS and ETASU should be removed in whole or in part based on criteria under 21 U.S.C. § 355-1(a)(1), (f)(1).” *Id.* at 21.

On the merits, the Plaintiff States will argue that FDA failed to consider the fundamental issue of whether mifepristone meets the statutory criteria for a REMS with ETASU *at all*. They will further argue that the particular ETASU that FDA

1 imposed are medically unnecessary, do not conform to the restrictions on similar
 2 or more dangerous drugs, and are unduly burdensome, especially for underserved
 3 patient populations, and that they therefore fail the statutory test and are arbitrary
 4 and capricious. *See* ECF No. 80 at 19-20 (quoting 21 U.S.C. § 355-1(f)(2)(C)-(D)).
 5 The missing documents at issue will support these arguments, which go to whether
 6 FDA meaningfully *considered* these issues, not FDA’s weighing of the evidence.
 7 *See id.* at 21 (“It is not the Court’s role to review the scientific evidence and decide
 8 whether mifepristone’s benefits outweigh its risks without REMS and/or
 9 ETASU. . . . However, based on the present record, FDA did not assess *whether*
 10 mifepristone qualifies for REMS and ETASU . . .” (emphasis added)).

11 The missing documents show, among other things, that FDA disregarded
 12 evidence—such as the 2022 Canada study—showing that lifting the REMS would
 13 not impact mifepristone’s safety profile, and that FDA failed to grapple with the
 14 impacts of the unnecessary and discriminatory REMS on underserved patients.
 15 Whether the REMS is “necessary to ensure that the benefits of the drug outweigh
 16 the risks” (i.e., whether it produces different safety outcomes than normal
 17 prescribing) and whether it is “unduly burdensome” are central questions that FDA
 18 is not at liberty to ignore. 21 U.S.C. § 355-1(a)(1), 21 U.S.C. § 355-1(f)(2)(C)-(D).
 19 Thus, the request for supplementation fits comfortably within even the narrower
 20 standard adopted by some district courts: the missing documents do not reflect
 21 mere “nuanced points” or “specific hypotheses/ conclusions,” but show that FDA
 22 overlooked “a general subject matter that is subject to the agency’s decision[.]”

1 *E.g., Nw. Env't Advocs. v. U.S. Fish & Wildlife Serv.*, No. 3:18-cv-01420-AC,
 2 2019 WL 6977406, at *7 (D. Or. Dec. 20, 2019); *see* ECF No. 139 at 12-13.

3 Next, and contrary to FDA's argument, its consideration of "Canada's
 4 experience" with one aspect of mifepristone prescribing does not absolve FDA
 5 from considering studies before it that bear on other REMS restrictions. *Contra*
 6 ECF No. 139 at 13. FDA points to its 2021 REMS Modification Rationale Review,
 7 in which it discussed a 2020 Canadian study that compared outcomes of
 8 telemedicine versus in-clinic visits for medication abortion. ECF No. 140-1 at 26-
 9 27 & 43 n.7. But FDA's consideration of this single 2020 study on telemedicine
 10 cannot somehow justify its complete failure to consider a *different* Canadian study,
 11 published in 2022, demonstrating that provider certification, a patient agreement
 12 form, and pharmacy certification do nothing to increase mifepristone's safety.
 13 ECF No. 61-1 at 18 (discussing a 2022 study after "Canada removed all restrictions
 14 on prescribing mifepristone for abortion, thereby allowing it to be prescribed and
 15 dispensed like any other drug").

16 Finally, FDA's suggestion that the Plaintiff States "request a new agency
 17 action," ECF No. 139 at 14, is disingenuous. This Court already found that filing
 18 another citizen petition to seek a different outcome would be futile. The instant
 19 Motion is limited to documents of which FDA was well aware when it imposed
 20 the current REMS, and which are necessary to resolve this case.

21 **III. CONCLUSION**

22 The Plaintiff States' Motion should be granted.

1 DATED this 9th day of February 2024.

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CERTIFICATE OF SERVICE

I hereby certify that on February 9th, 2024, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System, which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system. The NEF for the foregoing specifically identifies recipients of electronic notice.

DATED this 9th day of February 2024, at Seattle, Washington.

/s/ Kristin Beneski

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